Application No.: 10/656,797 15 Docket No.: 578492001500

# **REMARKS**

Claims 1-60 are pending in the present application. Claims 1-34, 37-45, 51, 52, and 54-60 were previously withdrawn from consideration as drawn to a non-elected invention or species. By virtue of this response, no claims have been cancelled, and no new claims have been added. Accordingly, claims 1-34, 37-45, 51-52, and 54-60 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

# Election/Restriction

Applicant affirms that in a telephone call on August 16, 2006 with the Examiner, Species III (Figures 5A-8) was elected without traverse. The claims readable thereon include claims 35-36, 46-50, and 53.

# Objections to the Specification

The disclosure has been objected to because of minor informalities. Specifically, the Office Action points out that on page 8, line 4, "a" should read "an"; on page 9, line 13, "allowing" should read "allow"; on page 10, line 3, "deliver" should read "delivery"; on page 12, line 26, "hay" should read "may"; on page 13, line 14, "an" should read "a"; and on page 14, line 2, "that" should read "than." Applicant thanks the Examiner for a careful review of the specification and has amended the specification to correct these informalities as noted above in the Amendments to the Specification. Accordingly, Applicant respectfully requests that the Objections to the Specification be withdrawn.

# Claim Rejections under 35 U.S.C. §102(b)

# Claims 35-36

Claims 35-36 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,843,169 to Taheri ("Taheri"). Specifically, the Office Action relies upon FIG. 1a of

Taheri as support for Taheri disclosing an elongate body and stabilizing member at the distal end of that body, where the stabilizing member is positionable under one or more leaflets of a valve of the heart to engage a length of the annulus along an intersection between at least one leaflet and an interior ventricular wall of the heart. Applicant disagrees with this rejection.

In order for a reference to serve as a basis for a rejection under 35 U.S.C. §102(b), it must teach or disclose each and every element of the rejected claims. Here, claim 35 (from which rejected claim 36 depends) requires that the stabilizing member be positionable under one or more leaflets of a valve of the heart "to engage a length of the annulus along an intersection between at least one leaflet and an interior ventricular wall of the heart." As described throughout Applicant's specification, the stabilization member of the present invention helps stabilize the valve annulus with respect to the rest of the beating heart during a minimally invasive percutaneous valve replacement procedure. The intersection of a leaflet and an interior ventricular wall of the heart is a very specific location, nowhere mentioned (or even alluded to) by Taheri, *see*, *e.g.*, FIGS. 1A-1B, and 3-5 of Applicant's specification.

Taheri simply does not teach a stabilizing device that is positionable under one or more leaflets of the heart to engage a length of the annulus along an intersection between at least one leaflet and an interior ventricular wall of the heart. In fact, Taheri does not speak to minimally invasive percutaneous valve repair at all. Instead, Taheri teaches methods and apparatuses for stapling graft material to the aortic wall while preserving the patency of the aortic branch orifices. The device of Taheri is configured for a different purpose, in a different location within the heart. Accordingly, Applicant respectfully submits that the rejections of claims 35-36 under 35 U.S.C. §102(b) are improper and should be withdrawn.

# Claim Rejections under 35 U.S.C. §103(a)

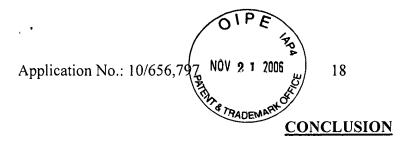
# Claims 46-50 and 53

Claims 46-50 and 53 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Taheri, as applied to claim 35 above, in view of U.S. Pub. No. 2002/0087169 to Brock et al.

("Brock"). Specifically, the Office Action states that Brock discloses a flexible instrument to deliver anchors using a balloon. Applicant disagrees with this rejection.

In order to set forth a *prima facie* case of obviousness, the references must teach or suggest all the claim limitations, there must be some suggestion or motivation to modify the references or combine their teachings, and there must be a reasonable expectation of success, *see* MPEP §2143. The Office Action fails to set forth a *prima facie* case of obviousness for at least the reason that the combination of Taheri and Brock does not teach or suggest all the claim limitations.

As described above with respect to independent claim 35, Taheri fails to teach a stabilization member positionable under one or more leaflets of a heart valve to engage a length of annulus along an intersection between at least one leaflet and an interior ventricular wall of the heart. Brock fails to cure this deficiency. Indeed, as shown throughout Brock's figures, and described throughout Brock's specification, the delivery of the anchors occurs in a supra-annular (not sub-annular) fashion, *see*, *e.g.*, FIG. 32, showing anchors being delivered from above the annulus. Indeed, there is not a single mention in Brock of any device positionable under one or more leaflets of a valve to engage a length of the annulus along an intersection between at least one leaflet and an interior ventricular wall of the heart. Accordingly, Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) is improper and should be withdrawn.



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In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 578492001500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: November 21, 2006

Respectfully submitted,

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